II. REMARKS/ARGUMENTS

A. Status of Claims

New claims 68 to 73 were added. Applicants submit that support for new claims can be found, e.g., on page 18, lines 21-30, of the original specification.

Claims 38 and 47-73 will be pending once the present amendment is entered.

Applicants submit that the elected invention and the elected species are encompassed by claims 38 and 47-73.

B. 35 U.S.C. §103 Rejection over U.S. Patent No. 4,569,937 to Baker et al.; Friedel et al. (Drugs, 1993. Vol. 45(1), pp. 131-156); and Eversmeyer et al. (American Journal of Medicine, Aug. 1993, Vol. 95, pp. 10S-18S).

Claims 38, 47, 48, 50-52, 62, 63 and 66 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 4,569,937 to Baker et al. ("the Baker patent"), Friedel et al. (Drugs, 1993. Vol. 45(1), pp. 131-156); and Eversmeyer et al. (American Journal of Medicine, Aug. 1993, Vol. 95, pp. 10S-18S).

The rejection is traversed, for the reasons presented in the response filed on April 10, 2009, hereby incorporated by reference, and the reasons given below.

Independent claim 38 is directed in part to a method of treating pain by administering nabumetone in combination with oxycodone to a human patient as recited in claim 38.

Applicants respectfully submit that the combination of the cited references does not teach or suggest administering nabumetone together with oxycodone, e.g., because the Friedel and Eversmeyer articles (which were relied upon by the Examiner for the

teaching of nabumetone) describe administration of nabumetone by itself, without any additional analgesic agents. Applicants further submit that there is nothing in the cited references to suggest that administration of nabumetone by itself will not produce adequate analgesia. Accordingly, Applicants submit that the combination of the cited references does not teach or suggest administration of nabumetone in combination with oxycodone as recited in claim 38.

In response to the Examiner's reliance on the case law on pages 14 and 17 of the Office Action, Applicants respectfully note that the claims at issue in the relied upon cases were not directed to a method of treating pain in a human patient, and that the Examiner's reliance on these cases may therefore be inappropriate.

Accordingly, Applicants submit that claim 38 and its dependent claims are not rendered obvious by the combination of the cited references.

With further regard to claim 50, Applicants submit that the combination of the cited references does not provide a reason for combining nabumetone with a pharmaceutically acceptable excipient "which provides a sustained release of nabumetone" as recited in claim 50, e.g., because the Friedel article describes a mean elimination half-life of, e.g., 38.8 and 26.3 hours, after administration of a single dose of 1 g of nabumetone. See the Friedel article, page 141.

Withdrawal of the rejection is respectfully requested.

With further regard to new claims 68 and 69, Applicants respectfully submit that the combination of the cited references does not teach or suggest administering "from 25 mg to 300 mg of nabumetone" or "100 mg of nabumetone" as recited in these claims, e.g., because the Friedel and Eversmeyer articles describes administration of much higher doses of nabumetone (e.g., 500 mg to 2000 mg).

C. 35 U.S.C. § 103 (a) Rejection over Baker et al., Friedel et al. and Eversmeyer et al. in view of Oshlack et al. (US 5,472,712) or Oshlack et al. (US 6,294,195)

Claims 38 and 47-67 were rejected under 35 U.S.C. § 103(a) over the Baker patent, Friedel et al. and Eversmeyer et al., and Oshlack et al. (US 5,472,712) or Oshlack et al. (US 6,294,195).

The rejection is traversed, for the reasons presented in the response filed on April 10, 2009, hereby incorporated by reference, and the reasons given below.

Independent claims 38, 53 and 62 are all directed in part to a method of treating pain by administering nabumetone in combination with oxycodone to a human patient as recited in these claims.

Applicants respectfully submit that the combination of the cited references does not teach or suggest administering nabumetone together with another analgesic (i.e., oxycodone), e.g., because the Friedel and Eversmeyer articles (which were relied upon by the Examiner for the teaching of nabumetone) describe administration of nabumetone by itself, without any additional analgesic agents. Applicants further submit that there is nothing in the cited references to suggest that administration of nabumetone by itself will not produce adequate analgesia. Accordingly, Applicants submit that the combination of the cited references does not teach or suggest administration of nabumetone in combination with oxycodone as recited in claims 38, 53 and 62.

Withdrawal of the rejection is respectfully requested.

With regard to new claims 68 to 73, Applicants respectfully submit that the combination of the cited references does not teach or suggest administering "from 25 mg to 300 mg of nabumetone" or "100 mg of nabumetone" as recited in these claims, e.g., because the Friedel and Eversmeyer articles describes administration of much higher doses of nabumetone (e.g., 500 mg to 2000 mg).

D. Rejection under 35 U.S.C. § 103(a) over U.S. Patent No. 5,840,731

Claims 38, 47-52 and 62-65 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,840,731 to Mayer et al., and if necessary in view of Friedel and Eversmeyer.

The rejection is traversed, for the reasons presented in the response filed on April 10, 2009, hereby incorporated by reference, and the reasons given below.

Independent claims 38 and 62 are all directed in part to a method of treating pain by administering nabumetone in combination with oxycodone to a human patient as recited in these claims.

Applicants respectfully submit that the combination of the cited references does not teach or suggest administering nabumetone together with another analgesic (i.e., oxycodone), e.g., because the Friedel and Eversmeyer articles (which were relied upon by the Examiner for the teaching of nabumetone) describe administration of nabumetone by itself, without any additional analgesic agents. Applicants further submit that there is nothing in the cited references to suggest that administration of nabumetone by itself will not produce adequate analgesia.

Applicants further submit that a dosage form in accordance with the Mayer patent will necessarily include "a nontoxic N-methyl-D-aspartate receptor antagonist," e.g., because the Mayer patent states that "the analgesic effectiveness of known combination drugs containing at least one analgesic drug can be significantly enhanced by the addition of a nontoxic N-methyl-D-aspartate receptor antagonist." *See e.g., column 2, lines 30-34.* Applicants therefore submit that the Mayer patent (alone or in combination with the Friedel and Eversmeyer articles) does not therefore provide a reason for the skilled person to formulate a dosage form without "a nontoxic N-methyl-D-aspartate receptor antagonist."

"A nontoxic N-methyl-D-aspartate receptor antagonist" is excluded from the scope of the rejected claims, by virtue of the "consisting of" language recited in independent claims 38 and 62. These claims are not therefore rendered obvious by the combination of the cited references, because the mandatory ingredient of the primary reference (i.e., "a nontoxic N-methyl-D-aspartate receptor antagonist") is excluded from the scope of the rejected claims.

For the foregoing reasons, Applicants submit that the combination of the cited references does not render independent claims 38 and 62 and their dependent claims obvious.

Withdrawal of the rejection is respectfully requested.

With further regard to new claims 68, 69, 72 and 73, Applicants respectfully submit that the combination of the cited references does not teach or suggest administering "from 25 mg to 300 mg of nabumetone" or "100 mg of nabumetone" as recited in these claims, e.g., because the Friedel and Eversmeyer articles describes administration of much higher doses of nabumetone (e.g., 500 mg to 2000 mg of nabumetone).

III. CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully requested to contact the undersigned at the telephone number provided below in the event that a telephonic interview will advance the prosecution of the application.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____
Oleg Iosilevich, Reg. No. 56,963

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, NY 10018
Tel: (212) 736-1940